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IN THE

Supreme Court of the United States

October Term, 1981

INWOOD LABORATORIES, INC. and
PREMO PHARMACEUTICAL LABORATORIES, INC.,

Petitioners,

vs.

IVES LABORATORIES, INC.,

Respondent.

REPLY BRIEF OF PETITIONER PREMO PHARMACEUTICAL LABORATORIES, INC.

PETER T. COBRIN
KIRSCHSTEIN, KIRSCHSTEIN,
OTTINGER & COBRIN, P.C.
Attorneys for Petitioner
Premo Pharmaceutical Laboratories, Inc.
666 Fifth Avenue
New York, New York 10103
(212) 581-8770

Of Counsel:
DAVID B. KIRSCHSTEIN
MARTIN W. SCHIFFMILLER

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Introduction

This brief is submitted by Petitioner Premo Pharmaceutical Laboratories, Inc. ("Premo") to reply to certain of the statements and propositions set forth by Respondent ("Ives") in its brief and by certain of the *amici*.

POINT I

The Argument Advanced by Ives That Compelling Petitioners to Change the Color of Their Cyclandelate Products Will Prevent Deception of the Public Is Untenable.

Ives in its brief goes to great length to urge that the only way to prevent deception of a consumer who receives Petitioners' products is by compelling Petitioners to change the color of said products. This argument is wholly illogical in that Ives does not set forth what type of deception it is referring to. The district court found that ". . . Ives failed to show that the colors indicate sponsorship or origin and have therefore acquired a secondary meaning." (Pet. App. 64a). This finding was not disturbed by the Court of Appeals in its opinion and was amply justified by the trial record before Judge Nickerson. Inasmuch as the colors of Ives' CYCLOSPASMOL product do not indicate a source of origin, one is left with the inevitable conclusion that the only function they serve for the patients who ingest them is to indicate a type of medication they are taking.

By forcing Petitioners to sell their cyclandelate products in different colors, the consumer will not think he is getting medication from a different manufacturer or source of origin since, as the trial record found, the colors do not indicate a source of origin. The only effect upon the consumer will be to make him think he is getting a different type of medication, i.e., a medication for a different therapeutic effect from that he had previously taken. If Petitioners are forced to sell cyclandelate in different colors, the only

deception to the consumer will be that he will be confused and deceived as to the true therapeutic effect of his medicine since the only function color serves to the consumer is to indentify a therapeutic activity, i.e., heart pill, water pill, pain pill, etc.

In an attempt to bolster its position that the trademark CYCLOSPASMOL identifies Ives as the source of origin, a claim is made on page 50 of Ives' brief that extensive sales of CYCLOSPASMOL and corresponding promotion establish secondary meaning.* However, the sales of Ives' product do not in any way establish secondary meaning inasmuch as the customer has no choice in the selection of

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*On p. 51 of its brief, Ives urges that its survey established that secondary meaning was shown. For the reasons advanced by the district court and for several other reasons, this argument of Ives must fail. In the survey conducted by Ives, a small number of those interviewed associated the color of Ives' product with the word "CYCLOSPASMOL". However, Ives failed to adduce any proof that these interviewees realized that CYCLOSPASMOL was a brand name or indicated a source of origin for the drug. Premo does not dispute that as to physicians and those in the health field CYCLOSPASMOL indicates Ives' drug. But there is no reason to assume that this applies at the consumer level. While the district court did not pass directly upon the merits of Ives' survey which dealt with secondary meaning, there was ample evidence before the trial court to disregard the survey in its entirety. In the first instance, Ives' survey was irrelevant because it did not purport to establish secondary meaning at the time the Petitioners entered the market with their look-alike generic cyclandelate products. It is axiomatic that "secondary meaning must have been established when the alleged infringer entered the market." *Le Sportsac, Inc.* v. *Dockside Research, Inc.*, 478 F.Supp. 602, 608 (S.D.N.Y. 1979). *See also Lucien Lelong, Inc.* v. *Lander Co.*, 164 F.2d 395, 397 (2d Cir. 1947) (secondary meaning must have been established when the defendants entered the field); *Maternally Yours* v. *Your Maternity Shop*, 234 F.2d 538, 544 (2d Cir. 1956); *Federal Glass Co.* v. *Loshin*, 224 F.2d 100, 101 (2d Cir. 1955). In addition, Ives refused to provide Petitioners with the names of the survey interviewees, which prevented Petitioners from taking suitable discovery, all in violation of the principles set forth in the *Manual for Complex Litigation*, 1 Moore's Federal Practice, Pt. 2.

the product and does not ask for Ives' drug. Still further, Ives admits on page 5 of its brief that its CYCLOSPASMOL is not advertised to the public.

Ives' concern as to how the consumer will know what drug he is getting is a bogus issue. At the time the physician prescribes the drug the physician will tell the inquiring patient what the drug is and whether or not a generic will be dispensed. This will give the patient the information he needs to have concerning what drug his doctor wishes dispensed. In addition, the patient can ask the pharmacist whether a generic is being dispensed. The suggestion by Ives that the only way the patient can tell what drug is being dispensed is by the color is simply not so, particularly in view of the fact that patients only regard color as a means of indicating a type of therapeutic activity.

POINT II

Ives' Argument Concerning Functionality Presents a One-Sided and Distorted View of the Trial Record.

Ives in its brief (pp. 11-15) discusses the question of functionality in a one-sided fashion that does not accurately reflect the testimony that was presented to the district court. It is beyond purview that Ives presented testimony to the district court that the color of the cyclandelate products was nonfunctional and Petitioners presented conflicting testimony. After hearing all of the testimony concerning this issue, Judge Nickerson found the drug colors to be functional and his finding was clearly supported by the record.

Dr. Judith Taylor, a neurologist, testified from personal experience that patients rejected taking a less expensive non-look-alike drug and that in her experience patients rely upon the appearance of a drug product as assurance that they are receiving the proper medication (JA 209a-211a).

Dr. Kent O. Shinbach, a psychiatrist who was called to testify on behalf of Petitioners, testified that patients rely on the color and appearance of capsules and tablets to assure themselves that they are receiving the proper medication. When patients receive medication with an unfamiliar appearance, "They suspect that I have written the wrong dosage. They think something is wrong and they want to know what is going on." (JA 293a).

Dr. Jerry Bloom, an internist, has prescribed CYCLOSPASMOL for his patients (Tr. 733) and testified that it is desirable from a medical standpoint for generic cyclandelate to be in the same size, shape and color as CYCLOSPASMOL (Tr. 735).

Cyclandelate is frequently prescribed for elderly patients who may exhibit symptoms of forgetfulness, disorientation, confusion, etc. and who have become accustomed to the appearance of the cyclandelate capsules (Shinbach JA 286a-290a). Such patients are frequently self-medicating, despite the aforementioned symptoms, because the degree to which these symptoms appear may not be severe or because the patient may live alone and there is no practical alternative to self-medication (Fine Tr. 45B-46B; Lehman JA 196; Taylor JA 205a-206a; Bloom JA 252a; Shinbach JA 286a-287a). Elderly patients such as those

for whom cyclandelate is prescribed frequently take more than one medication each day and may be self-medicating with different medicines (Fine JA 114a; Lehman JA 196a; Taylor JA 205a; Shinbach JA 287a). Frequently, patients commingle their medications, relying on the color to comply with their physicians' instructions regarding frequency of usage (Fine JA 115a-116a; Taylor JA 205a-207a; Bloom JA 252a-253a; Shinbach JA 288a-289a).

The colors of capsules are also frequently used by doctors and pharmacists in communicating with their patients who regularly refer to pills by colors; *e.g.*, "my red heart pill," "my blue stroke pill," etc. (Taylor JA 207a-208a; Shinbach JA 289a-290a). Obviously, such communication would be hampered and subject to confusion and misunderstanding if patients were to receive cyclandelate capsules in different color combinations whenever a prescription was refilled.

Dr. Taylor, Dr. Shinbach and Ms. Gringauz testified about their personal experiences in which the color and appearance of drug capsules played a role in assisting emergency room physicians to identify the drug consumed by the patient (Taylor JA 211a-212a; Gringauz JA 239a; Shinbach JA 296a-298a).

While Premo does not claim that color is the most significant or can be the sole clue in identifying a drug in an emergency situation, there can be no doubt that it is of some value. If generic drugs were required to be sold in colors different from their well-known brand name counterparts, this value would be lost in a plethora of confusing colors and color combinations for identical drugs.

It can thus be seen that while there was undoubtedly conflicting testimony presented to the trial court as to whether or not the drug colors were functional, the district court resolved this conflicting testimony in support of Petitioners' position.* The Court of Appeals did not even pay lip service to the district court's findings.

POINT III

Ives' Proposition That Pharmacists Are Dishonest and Cannot Be Trusted Is Unsupported by the Record.

Ives' entire theory of contributory trademark infringement boils down to one simple proposition: that pharmacists cannot be trusted to sell look-alike drugs since they will use them for illegal substitution. Ives also argues (page 23 of its brief) that the widespread instances of unlawful substitution by pharmacists has spawned many lawsuits. These statements by Ives are totally unsupported by the record. In support of its position that there have been many lawsuits with respect to illegal substitution since 1924, when the *Warner* case was decided by this Court, Ives has only been able to identify a handful of cases. Ives' position that pharmacists inherently cannot be trusted and engage in widespread acts of illegal substi-

* The argument advanced by the Pharmaceutical Manufacturers' Association that the question of functionality is a matter of law is frivolous. The fact that different courts have reached different conclusions with respect to this question merely highlights the significance that should be attributed to the district court's careful evaluation of all relevant testimony. In *Ives II*, Judge Friendly specifically held that functionality was a factual question, stating: "The case for functionality thus depends on the evidence proffered by defendants that copying whatever colors Ives had chosen served a number of utilitarian purposes. . . ." (Pet. App. 50a).

tution is at variance with the testimony of its witness, Brendon Lawlor, a practicing pharmacist and President of the New York State Pharmaceutical Society, who testified that, based upon his experience, there was little evidence of illegal substitution by pharmacists* (JA 182a).

In any event, it is clear that for the reasons enumerated by the district court the copying of colors serves a beneficial purpose and, to the extent that any licensed professional may illegally substitute, he is subject to disciplinary provisions by his licensing board.

Ives in its brief attempts to bolster its position that there is widespread illegal substitution by referring to the March 13, 1979 report of the Attorney General of the State of New York (page 11 of its brief). Specifically, Ives urges that the report shows nearly one-quarter of the pharmacists in New York violate the generic drug law in filling prescriptions and do not pass full savings along to the consumer. This statement by Ives is out of context. What the report held was that the pharmacists are not making required substitutions when directed to do so by the prescribing physicians and as such the pharmacist is not passing along to the consumer the lower price of the generic drug.

Ives on page 27 states that there are over 3,000 pharmacies in the State of New York, implying that it should not

* The statement in the footnote on page 36 of Ives' brief that the potential for deception and confusion is shown by Ms. Gringauz filling Medicaid brand name prescriptions with generic drugs is disingenuous. Ms. Gringauz testified that in the hospital where she is employed she has prior written consent from every doctor on the staff giving her the option to dispense generically when filling a prescription (Tr. 715).

be expected to sue each one. This statement by Ives is outrageous in its attempt to implicate all the pharmacists in New York State as being involved in illegal substitution. As Ives has demonstrated in this lawsuit, it is an easy matter to locate those pharmacies who are engaged in mislabelling generic look-alikes and there is no reason why it cannot initiate lawsuits against those pharmacies as it did in this case. The argument that there are 3,000 pharmacies should not be a basis for allowing Ives to use its word trademark CYCLOSPASMOL to enjoin Petitioners from selling their look-alike products when this Court has traditionally held that colors cannot be protected.*

POINT IV

Ives Is Incorrect When It Urges That Petitioners Can Compete Equally as Well by Selling Their Drug Products in Different Colors.

The very intensity with which Ives has prosecuted this suit and with which the large drug manufacturers have attempted to preserve their monopoly on drug colors belies the claim that Petitioners could compete equally as well in different colors. Certainly no one believes that Ives has prosecuted this suit because of an altruistic concern for the consumer. The reason Ives has prosecuted this suit is that Petitioners are able to compete more effectively by selling their generic products as look-alikes and the reason

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* *A. Leschen & Sons Rope Co.* v. *Broderick*, 201 U.S. 166, 170-71 (1906); *American Basketball Assoc.* v. *A.M.F. Voit, Inc.*, 358 F. Supp. 981, 985 (S.D.N.Y.), *aff'd without opinion*, 487 F.2d 1393 (2d Cir. 1973), *cert. denied*, 416 U.S. 986 (1974); *Plastilite Corp.* v. *Kassnar Imports*, 508 F.2d 824, 826 (C.C.P.A. 1975); *Diamond Match Co.* v. *Saginaw Match Co.*, 142 Fed. 727 (6th Cir. 1906); *Campbell Soup Co.* v. *Armour & Co.*, 175 F.2d 795 (3d Cir. 1949), *cert. denied*, 338 U.S. 847 (1949).

for this is quite simple. The consumer does not identify the color of the product with a source of origin but only with a therapeutic effect. Thus, a patient who has taken a drug during the life of the patent in one color and uses the color to identify the drug as his heart pill, upon receiving a drug with the same chemistry in a different color, will only assume he is not receiving a heart pill but a drug having a different therapeutic effect. This is why Petitioners cannot compete as effectively by selling non-look-alikes.

Ives in its brief argues the fact that SK&F sold a line of generics that were not look-alikes and therefore Petitioners should follow suit. However, testimony with respect to the SK&F line by the Chief Pharmacist of a New York hospital showed that some patients refused to take an SK&F drug thinking it was the wrong medication (JA 276a-278a).

POINT V

Ives' Argument Concerning the *Sears* and *Compco* Cases Is Disingenuous.

The argument advanced by Ives on page 39 of its brief concerning *Sears/Compco* is distorted. If this Court were to follow Ives' interpretation of *Sears* and *Compco,* then the pole lamp of the *Sears* case and the lighting fixture of the *Compco* case could not have been copied with impunity as this Court held.

As this Court noted in the *Sears* case:

> ". . . because of the federal patent laws a State may not, when the article is unpatented and uncopyrighted,

prohibit the copying of the article itself or award damages for such copying."

(376 U.S. 232-33).

The import of the *Sears* and *Compco* cases is clear. States may not use their unfair competition laws to give protection to that which is not protectable under the patent, trademark and copyright statutes. Ives in its argument concerning §43(a) of the Lanham Act is, in effect, trying to circumvent the rationale of the *Sears* and *Compco* cases by urging that §43(a) of the Lanham Act can be used as a basis for protection for that which otherwise would not be protectable under the patent, trademark or copyright statutes.

As Premo has pointed out on page 21 of its main brief, the use of §43(a) of the Lanham Act to eviscerate the holdings of the *Sears* and *Compco* cases is improper and this Court is again urged to rule on the question of whether §43(a) of the Lanham Act can be used to prevent copying the appearance of an article when such an appearance is not protectable under the patent, trademark or copyright laws. To allow §43(a) to be used as Ives suggests runs counter to Article II, Section 8, Clause 8 of the Constitution which provides that protection can only be had where such protection would promote the progress of science and the useful arts by authors and inventors. Under no circumstances could one consider the selection of a blue color or a blue and red color combination to be an invention or to be the work of an author.

POINT VI

The Argument by the PMA That Look-Alike Marketing Frustrates Consumer Choice Is Devoid of Merit.

In the PMA brief (page 20), an argument is made that look-alike marketing frustrates consumer choice. This argument totally misconstrues the nature of dispensing pharmaceutical drugs. Under New York State law [§6810(6)(a) of the Education Law], a prescription form must conspicuously state that the prescription will be filled generically unless the physician indicates otherwise. Two lines are then provided, one over the words "Substitution permissible" and the other over the words "Dispense as written".

Unless the physician otherwise directs, the pharmacist making a substitution must indicate on the label the name and strength of the drug and its manufacturer and where the brand name drug is dispensed, §6815(2)(j) requires the pharmacist to affix the brand name. Thus, it can be seen that the physician determines whether the patient receives a generic drug or a brand drug. The pharmacist will dispense a generic drug if the "Substitution permissible" line is signed by the physician and otherwise a brand drug. However, under New York State law the patient has no choice, once the prescription blank has been filled out, as to which drug is dispensed to him.

The argument by the PMA concerning consumer choice simply represents a misunderstanding of how prescription drugs are sold. They are not sold in New York by a consumer going into a drugstore and making a selection between a brand name or generic drug. When the patient comes into the store with a prescription he has no say in whether the pharmacist fills the prescription with a

branded drug or a generic product. While the freedom of choice argument advanced by the PMA might under some circumstances have relevancy where a consumer selects goods from a store shelf, it has no bearing whatsoever insofar as prescription drugs are concerned.

POINT VII

The Suggestion by the PMA That the Look-Alike Generic Drug Products May Endanger Public Health Is Not Supported by the Record.

The PMA in its brief urges on page 17 that look-alike drugs may endanger public health. This argument by the PMA has no relevancy to the case at hand. Ives has never once asserted any proof whatsoever that Petitioners' products have any different effect on the consumer than its product. Throughout this case all parties have treated the products of the Petitioners and Ives as being equivalent in all respects.

POINT VIII

The Suggestion by the PMA That Certiorari Was Improvidently Granted Is Frivolous.

The PMA's suggestion that the Court should dismiss the writ of certiorari as improvidently granted is not supported by fact or law. In taking a position which not even Ives has urged, the PMA has based its argument, set forth on pages 8, *et seq.* of its brief, on two premises: first, that the present case is a look-alike case in which the Court of Appeals only ruled on the contributory infringement claim, and second, that the parties have not briefed the §43(a) claim.*

* It is beyond purview that this Court has jurisdiction under 28 U.S.C. §1254(1).

The PMA's first argument is that since most look-alike cases are prosecuted under §43(a) and as the Court of Appeals did not rule on Ives' §43(a) claim, the "look-alike" issue is not properly before this Court. This argument totally ignores that there is a significant issue of contributory infringement before the Court that disposed of the look-alike issue and that Petitioners are under an injunction from selling their look-alike cyclandelate products. The look-alike issue now before this Court is in the context of a contributory trademark infringement claim which has been directly passed upon by the Second Circuit.

The §43(a) claim has been briefed by several of the parties (including Ives and Premo), discussed by the district court and Judge Friendly in *Ives II*, and Judge Mulligan in his dissent in *Ives IV*, and the principles that this Court lays down with respect to *Sears/Compco* and other questions concerning this case will definitely provide guidance to future courts concerning the application of §43(a) to look-alike cases.

Conclusion

The decision of the Court of Appeals under review should be reversed.

Respectfully submitted,

PETER T. COBBIN
KIRSCHSTEIN, KIRSCHSTEIN,
OTTINGER & COBBIN, P.C.
Attorneys for Petitioner
Premo Pharmaceutical Laboratories, Inc.
666 Fifth Avenue
New York, New York 10103
(212) 581-8770

Of Counsel:
DAVID B. KIRSCHSTEIN
MARTIN W. SCHIFFMILLER